K984235

8 510(K) SUMMARY

8.1 General Information

Applicant:	IBt, Inc. 6000 Live Oak Parkway, Suite 107 Norcross, GA 30093 Tel: (770) 582 0662 Fax: (770) 582 0657
Contact Person IBt, Inc.:	Ruth Feicht
Establishment Registration Number:	9035105 (IBt, Inc.)
Manufacturing Site:	IBt SA Zone Industrielle C 7180 Seneffe – Belgium Tel: (+32) 64 / 520 811 Fax: (+32) 64 / 520 801
Contact Person IBt SA:	Vincent Coniglione
Establishment Registration Number:	9031509 (IBt SA)
Classification Name:	Radionuclide Brachytherapy Source
Common/Usual Name:	Iodine-125 Seed
Proprietary Name:	InterSource^{125} (InterSource^{125} is a Trademark of IBt SA.)
Model Number:	1251L
Establishment Registration Number:	9035105 (IBt, Inc.)
Classification:	Class II, same as the predicate device (see the Substantial Equivalence section below for predicate device information)
Special Controls:	InterSource^{125} will comply with the regulatory requirements for the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Division for sealed brachytherapy implant sources.
Substantial Equivalence:	InterSource^{125} is substantially equivalent to the Amersham/Medi+Physics Model 6711 Therapeutic Seed Source (Premarket Notification #K914281), a Class II post-amendment device granted clearance to market on 22 Nov 1991.

8.2 The contents of this premarket notification summary will demonstrate the substantial equivalence of the subject device, InterSource^{125}, to the predicate device, the Amersham/Medi+Physics Model 6711 Therapeutic Seed Source. The substantial equivalence will be based on the following important features of the device:

- 8.2.1 Indications
- 8.2.2 Physical Size
- 8.2.3 Radiopaque Marker
- 8.2.4 Biocompatibility
- 8.2.5 Radioisotope
- 8.2.6 Radiation Dose

8.3 InterSource^{125} Description

InterSource^{125} is a hermetically sealed radiotherapeutic source indicated for interstitial implantation. The radionuclide used in InterSource^{125} is Iodine-125 (I-125). InterSource^{125} is constructed by placing a platinum / iridium radiopaque marker and I-125 on the surface of a medical grade titanium inner tube. The device is sealed by sliding an outer tube, also medical grade titanium, over the inner tube and laser welding both ends. The resulting device has a hollow center with an inner diameter of 0.37 mm with all body tissue contacting surfaces made from medical grade titanium.

8.4 Table 6 compares the indications statement drafted for InterSource^{125} with the predicate device's indications statement.

Table 6: Indications Statement Comparison Summary

InterSource^{125}	Predicate Device
InterSource^{125} implants are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor. InterSource^{125} implants are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy.	I-125 Seeds are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, slow growth rate, and low to moderate radiosensitivity. I-125 Seeds may be used to treat superficial, intraabdominal or intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated. I-125 Seeds are indicated to treat residual tumors following completion of a course of external radiation therapy. In addition, recurrent tumors may be implanted with I-125 Seeds.

8.5 Based on the intent of the indications statement for the subject device, InterSource^{125} is substantially equivalent to the predicate device with respect to its indications.

8.6 Table 7 compares the physical size, radiopaque marker, materials of construction, and the radioisotope for the subject device and the predicate device.

Table 7: Feature Comparison

Feature Description	InterSource^{125}	Predicate Device
Outer Tube	Medical grade titanium	Titanium
Length	4.5 mm	4.5 mm
Outside Diameter	0.8 mm	0.8 mm
Radiopaque Marker	Platinum / Iridium	Silver
Isotope Carrier	Medical grade titanium	Silver
Inner Tube	Medical grade titanium	Not Applicable
Seal Method	Laser Weld	Plasma Arc Weld
Radioisotope	Iodine-125	Iodine-125

Half-life	59.4 days	59.4 days
Principal Energy Levels	27.2 keV, 27.5 keV 31.0 keV, 35.5 keV	27.2 keV, 27.5 keV 31.0 keV, 35.5 keV
Distribution of Isotope	Deposited onto the surface of the isotope carrier	Deposited onto the surface of the isotope carrier
Apparent Activity Levels	0.1 to 5.0 mCi	0.18 to 5.99 mCi
Residual Activity	< 1.1 µCi at 2 years	< 1.3 µCi at 2 years

8.7 Based on the outside dimensions of the subject device being the same as the predicate device, both devices having a radiopaque marker, the body tissue contacting materials being made of a known biocompatible material, titanium, and both devices using Iodine-125 as the radionuclide, the subject device, InterSource^{125} is substantially equivalent to the predicate device with respect to the physical size, presence of a radiopaque marker, biocompatibility, and radioisotope used.

8.8 The radiation dose of InterSource^{125} and the therapeutic effect of the ionizing radiation emitted are characteristics of the radionuclide used, Iodine-125, and the shape and placement of the internal components. Figure 5 shows the computed values for the radiation dose delivered by InterSource^{125} and the measured values for the radiation dose delivered by the predicate device (as previously published) as a function of angle.

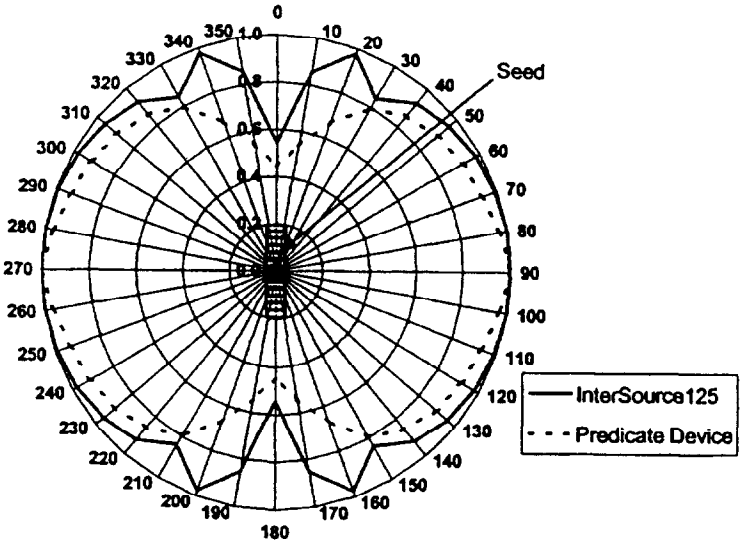

Figure 5: InterSource^{125} Distribution of Radiation Dose

8.9 Based on InterSource^{125} and the predicate device having a similar distribution of radiation dose and using the same radioisotope, InterSource^{125} is substantially equivalent to the predicate device with respect to radiation dose.

8.10 Substantial Equivalence Summary

8.10.1 Based on the similar characteristics for indications, physical size, radiopaque marker, biocompatibility, radioisotope, and radiation dose between the subject device, InterSource^{125}, and the predicate device, InterSource^{125} is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 1999

Ruth Feicht
President
International Brachytherapy, Inc.
6000 Live Oak Parkway, Suite 107
Norcross, GA 30093

Re: K984235
InterSource^{125} Radionuclide Brachytherapy Source
Dated: March 10, 1999
Received: March 12, 1999
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Ms. Feicht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K984235

Device Name: InterSource^{125}

Indications For Use:

InterSource^{125} implants are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor. InterSource^{125} implants are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984235

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)